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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,861	03/31/2004	Edward Vaquero	P03505	5583
23702 7590 09/16/2010 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701				
EXAMINER				
NGUYEN, TUAN VAN				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
09/16/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,861

Applicant(s)

VAQUERO, EDWARD

Examiner

TUAN V. NGUYEN

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 18-23 and 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 13-15, 18-24 and 25-31 are pending in this present application.

This Office action is in response to the RCE filed on 7/22/2010.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/2010 has been entered.

Response to Amendment

According to the amendment filed on 7/22/2010, independent claim 13 has been amended and claims 32-33 are new.

Accordingly, claims 13-15, 18-2-33 are pending, claim 24 has been withdrawn and claims 13-15, 18-23, and 25-33 are presented for examination.

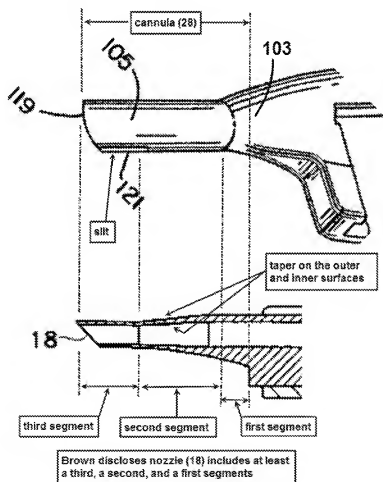
Response to Arguments

With respect to Applicant's arguments that "the Applicants note that none of the art of record suggests such a configuration. Rather, as stated above, Clark discloses a slot that extends into a single segment. Significantly, Clark teaches that such a configuration (without any modification) achieves the result that the Examiner sets forth as the rationale for modifying Clark (i.e., gradual return of the IOL to its original shape before it is released into the eye). Accordingly, the Examiner's rationale for modification is without merit". Examiner respect fully traverses applicant's remarks.

Note that Brown discloses (see Fig. 4, reproduced and annotated below this paragraph) an IOL injector comprising, among other things, a nozzle (18) or tip comprising at least a third segment (see annotated figure below) having a constant diameter, a second segment (see annotated figure below) having a taper located on the outer surface and a taper located on the inner surface of bore 16. Apparently, the advantage of having a taper on the outer and inner surfaces on the second segment is for gradually compressing the IOL to fit through a small distal tip, which is the third segment (see annotated figure below), thereby, facilitate insertion of the nozzle into a small incision in the ocular tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the shape of the elongate distal portion (105) of Clark to have a similar shape according to the nozzle (18) as suggested by Brown so that it too would have the same advantage. With respect to the limitation of "a slot extending from the open end through the second segment and the third segment", noting that the slit (121) as shown in Figure 3 of Clark reference is disposed at the distal tip and

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apparently, the slit extended substantially half way of the length of the elongate distal portion (105) (see annotated figure above). According to the annotated figure above, the shape of the elongate distal portion (105) of Clark reference as modified by Brown would includes a first segment, a second segment, a third segment and a slot extending from the open end through the second segment and the third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

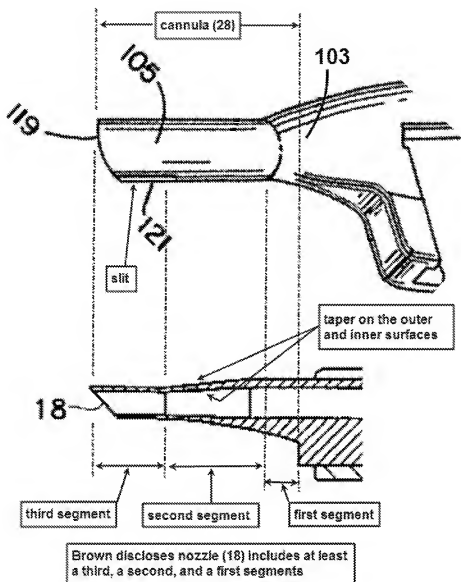
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-15, 18-23, 25, 26, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S. 6491697) in view of Brown et al (U.S. 6010510).

Regarding claim 13, Clark discloses (see Fig. 1) an injector for delivering a foldable IOL into an eye, comprising: a tubular member (22) or an injector body having a cannula (28) or a tip comprising a proximal funnel-shaped portion (103) or first segment, an elongate distal portion (105) or a third segment, the elongate distal portion (105) or the third segment extending to an open end (see Fig. 1, reference number 119) of the

injector body, the open end being adapted to permit the IOL (12) to exit the injector into the eye, at least one slit (121) or slot (see Figs. 2-3) extending from the open end through a portion of the elongate distal portion (105) (col. 3, lines 50-65; col. 4, lines 55-68; col. 5, lines 58-68; and col. 6, lines 30-50).

Clark discloses the invention substantially as claimed except for disclosing the elongate distal portion (105) of the cannula (28) further comprises a second segment, wherein the second segment connected to the third segment at the transition point, the transition point characterized by a discrete change in taper on the outer surface. However, Brown discloses (see Fig. 4, reproduced and annotated below this paragraph) an IOL injector comprising, among other things, a nozzle (18) or tip comprising at least a third segment (see annotated figure below) having a constant diameter, a second segment (see annotated figure below) having a taper located on the outer surface and a taper located on the inner surface of bore 16. Apparently, the advantage of having a taper on the outer and inner surfaces on the second segment is for gradually compressing the IOL to fit through a small distal tip, which is the third segment (see annotated figure below), thereby, facilitate insertion of the nozzle into a small incision in the ocular tissue.



It would have been obvious to one of ordinary skill in the art to modify the shape of the elongate distal portion (105) of Clark to have a similar shape according to the nozzle (18) as suggested by Brown so that it too would have the same advantage. With respect to the limitation of "a slot extending from the open end through the second segment and the third segment", noting that the slit (121) as shown in Figure 3 of Clark reference is disposed at the distal tip and apparently, the slit extended substantially half

way of the length of the elongate distal portion (105) (see annotated figure above).

According to the annotated figure above, the shape of the elongate distal portion (105) of Clark reference as modified by Brown would includes a first segment, a second segment, a third segment and a slot extending from the open end through the second segment and the third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper.

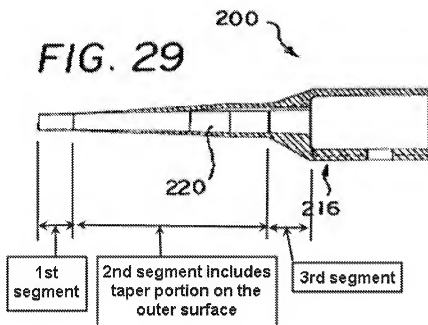
Regarding claims 15, 18-23, 25, 29, 30 and 31, Clark discloses (see Figs. 1-6C) the elongate distal portion (105) having a constant diameter and two slits (121) disposed at the distal region of the tip. A slanted face (119) located at the distal end of the elongate distal portion (105) and a lumen (107), which extends through cannula (28). The lumen (107) is axially aligned with passage (76) of compressing station (26) or loading bay. A compressor drawer (40) extending from the loading bay (26) for receiving the IOL, wherein the drawer comprises a groove (70) (Fig. 6A-6C), which is aligned with the lumen grooves (68) and 76 (col. 3, lines 50-65; col. 4, lines 55-68; col. 5, lines 58-68; and col. 6, lines 30-50).

Regarding claim 14, Clark/Brown discloses the invention substantially as claimed except for disclosing the third segment having a constant diameter of about 2.0 to 2.5 mm. However, it is old and well known to make the size of the insertion segment of an IOL injector as small as possible in order to obtain the advantage of facilitate insertion of the injector into the eye through a small incision in ocular tissue, thereby, minimizing the invasiveness of the procedure. It would have been obvious to so size the distal tip of

Clark/Brown to have a diameter of about 2.0 to 2.5 mm so that it too would have this advantage.

Regarding claims 26 and 27 (were 25 and 26), Clark/Brown discloses the first segment (103) (see annotated figure) is unslotted and the first segment has a different taper than the second segment (see Fig. 1 and annotated figure).

Claim 28 (was 27) stand rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. in view of Brown et al. as applied to claim 13 above and further in view of Feingold et al. (US 5,772,666). The modified device of Clark/Brown discloses the invention substantially as claimed except for disclosing the second segment has a constant outer diameter. However, Feingold discloses (Figs. 29-30, reproduced and annotated below) that the tip of an IOL injector includes first segment, second segment, and a third segment, wherein the second segment has a constant outer diameter and a taper portion between the first and second segment. Apparently, the advantage of providing the second segment with a constant outer diameter is to prevent the tip from stretching the incision in the ocular tissue. It would have been obvious to one of ordinary skill in the art to modify the second segment of Clark/Brown tip according to the suggestion of Feingold so that it too would have the same advantage.



Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/TUAN V NGUYEN/
Examiner, Art Unit 3731